

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220



## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

### FOR FURTHER ACTION

See paragraph 2 below

|   |  |  |
|---|--|--|
| International application No.<br>PCT/B2004/000536 | International filing date (day/month/year)<br>01.03.2004 | Priority date (day/month/year)<br>28.02.2003 |
|---|--|--|

International Patent Classification (IPC) or both national classification and IPC  
A61K9/20, A61K9/30, A61K31/4439

Applicant  
RANBAXY LABORATORIES LIMITED

#### 1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

#### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

#### 3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITYInternational application No.  
PCT/IB2004/000536

DT09 Rec'd PCT/PTO 26 AUG 2005

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
 This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:  
 a sequence listing  
 table(s) related to the sequence listing
  - b. format of material:  
 in written format  
 in computer readable form.
  - c. time of filing/furnishing:  
 contained in the international application as filed.  
 filed together with the international application in computer readable form.  
 furnished subsequently to this Authority for the purposes of search.
3.  In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/IB2004/000536

**Box No. II Priority**

1.  The following document has not been furnished:

- copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).  
 translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2.  This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or  
industrial applicability; citations and explanations supporting such statement**

1. Statement

|                               |             |      |
|-------------------------------|-------------|------|
| Novelty (N)                   | Yes: Claims | 1-39 |
|                               | No: Claims  |      |
| Inventive step (IS)           | Yes: Claims | 1-39 |
|                               | No: Claims  |      |
| Industrial applicability (IA) | Yes: Claims | 1-39 |
|                               | No: Claims  |      |

2. Citations and explanations

**see separate sheet**

**Re Item V.**

- 1 The following documents are referred to in this communication:

D1 : EP 1 004 305 A  
D2 : WO 98/52564 A

Document D1 (see Table III) discloses stable preparations comprising a core including sodium rabeprazole (50 mg) and HPC (450 mg).

Document D2 (see example 3) discloses cores including and active drug and small amounts of low viscosity HPC (HPC-L Klucel). On p. 4, l. 4 pariprazole (= rabeprazole) is disclosed as an example of an active drug.

- 2 The subject-matter of claims 1-22 (composition) and 23-39 (method) is novel (Art. 33(2) PCT) since a core comprising rabeprazole and at least 10% w/w of low viscosity HPC has not been disclosed in any of the available prior art documents.
- 3 The subject-matter of claim 1 differs from D1 (see above under item 1) in that it selects a particular HPC, namely low viscosity HPC.

There is no hint in D1 (alone or in combination with any other document) that more stable compositions of rabeprazole can be obtained when including at least 10% w/w of low viscosity HPC in the core. Therefore, the subject-matter of claims 1-39 is considered to involve an inventive step (Art. 33(3) PCT).